K022941

OCT 2 8 2002

Premarket Notification [510(k)] Summary
(21 CFR 807.92)

Submitted by: Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, Massachusetts 01730

Device Name: MediSense Precision PCx Point of Care Management System for Blood Glucose Testing
Common Name: Blood Glucose Testing System
Classification: Glucose Test System, Class II per 21 CFR 862.1345

Predicate Devices:

Precision PCx Point of Care Management System for Blood Glucose Testing (K982303) that uses the MediSense blood glucose test strip cleared under K971812.

Description:

The Precision PCx Point of Care Management System for Blood Glucose Testing utilizes amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of glucose present in the sample providing a quantitative measure of glucose in whole blood and control solutions.

Intended Use:

The Precision PCx Point of Care Management System for Blood Glucose Testing is intended for in vitro diagnostic use (i.e. for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The Precision PCx Point of Care Management System for Blood Glucose Testing is for home (lay user) or professional use. The PCx Point of Care Management System for Blood Glucose Testing is for monitoring blood glucose concentration in patients with diabetes mellitus or other conditions.

Healthcare professionals may also use the product for the quantitative measurement of glucose in venous, arterial or neonatal whole blood, provided the sample is used within 30 minutes.

Comparison to Predicate Device:

The changes to the Precision PC*x* Point of Care Management System for Blood Glucose Testing do not affect the technological characteristics or the intended use of the predicate Precision PCx Point of Care Management System (K982303) when using the test strips described in K971812.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 6 2002

Ms. Iris R. Gibbs
Senior Regulatory Affairs Specialist
Abbott Laboratories Inc.
MediSense Products
4A Crosby Drive
Bedford, MA 01730-1402

Re: k022941
Trade/Device Name: MediSense Precision PC*x* Point of Care Management System for Blood Glucose Testing
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: LFR
Dated: August 30, 2002
Received: September 3, 2002

Dear Ms. Gibbs:

This SE Letter corrects SE Letter K022941 dated October 28, 2002. It corrects the Product Code to read LFR. The letter dated October 28, 2002 had the Product Code as NBW which is incorrect. The letter is now correct.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number (if known): K022941

Device Name: MediSense Precision PC*x* Point of Care Management System for Blood Glucose Testing

Indications For Use:

The MediSense Precision PC*x* Point of Care Management System for Blood Glucose is intended for the in vitro diagnostic use (i.e. for external use only) for the quantitative measurement of glucose in fresh capillary whole blood. The MediSense Precision PC*x* Point of Care Management System is for home (lay user) or professional use. The PCx Point of Care Management System for Blood Glucose Testing is for monitoring blood glucose concentration in patients with diabetes mellitus or other conditions.

The product may also be used by healthcare professionals for the quantitative measurement of glucose in venous, arterial, or neonatal whole blood, provided that the sample is used within 30 minutes.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The-Counter Use ✓
(Per 21 CFR 801.108)

Ann Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022941